Remarks

Amendments to the Claims

Independent claims 1 and 6 have been amended to specify that the medication chamber has a smaller diameter than the diameter of the applicator barrel. Support for these amendments can be found in the specification at least at page 3, lines 29-30.

Rejection Under 35 U.S.C. § 103

Claims 1-8 and 9-10 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,027,471 to Fallon, et al. ("Fallon") in view of U.S. Patent No. 6,224,573 to Yeager *et al.* ("Yeager") and further in view of U.S. Patent No. 6,547,467 to Quintero, et al. ("Quintero"). It appears that the Examiner intended for this rejection to apply to claims 1-6 and 8-10 since claim 7 was previously canceled.

Legal Standard

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

Fallon

Fallon discloses a device for administering a particulate hemostatic agent onto living tissue, such as tissue in the abdominal cavity (*see* col. 1, lines 39-40 and 55-63). Fallon does not disclose or suggest a vaginal or rectal applicator, as required by claim 1 and its dependent claims. As shown in Figure 1, Fallon's device has a tapered tube (12) with a lumen (18) for holding the hemostatic agent. Tube (12) has a length of about 20 cm, and diameters of about 1.59 and 1.94 cm, respectively, for the smaller end and the larger end (col. 2, lines 33-36).

The structure of Fallon's device is clearly distinct from the claimed applicator. Fallon's device requires one continuous space that contains the hemostatic agent. In contrast, the claimed applicator contains an applicator barrel with a separate space forming a discrete medication chamber within the applicator barrel, where the medication chamber has a smaller diameter than the diameter of the applicator barrel. Fallon's applicator does not contain a discrete medication chamber within the tube (12).

Further, Fallon does not disclose or suggest an applicator that can be breech-filled, i.e. filled through the opening at the tip of the applicator. Fallon contains no teaching or suggestion to modify the applicator so that it can be breech-filled through the narrowest opening in the applicator. Additionally, Fallon does not disclose an upper limit to the volume of medicament that its applicator can hold.

Yeager

Yeager discloses a disposable applicator for dispensing a desired quantity of a substantially non-runny medicament. As shown in Figures 5-7, the device contains a housing

(14) which has a barrel portion (47), which includes a generally tapered tubular wall (48) defining a housing chamber (50). As shown in Figures 2 and 7, the term "housing chamber (50)" refers to the entire space inside the barrel portion (47) (*see also* col. 6, lines 4-6). Thus, the structure of Yeager's applicator is clearly distinct from the claimed applicator. Yeager requires an applicator with one continuous space that is filled to contain the medicament. In contrast, the claimed applicator contains an applicator barrel with a discrete medication chamber within the applicator barrel.

Further, Yeager does not disclose or suggest an applicator suitable for breech filling. Yeager discloses filling the entire housing chamber (50) of the applicator through the wide lower opening (64) with "a substantially non-runny medicament", and then placing the plunger in the applicator barrel (*i.e.* housing chamber) (*see* abstract and col. 5, lines 47-50 and 62-66). The medicament is placed in one, wide opening of the applicator, and then is administered to a patient through a narrower opening at the opposite end of the applicator.

In fact, Yeager teaches away from an applicator suitable for breech filling. Yeager indicates that his design, which requires placing the medicament in through a large opening, is well-suited for automated filling (*see* col. 5, lines 62-65). Yeager contains no teaching or suggestion to modify the applicator so that it can be breech-filled through the narrowest opening in the applicator. Further Yeager does not disclose or suggest an upper limit to the volume of medicament that the applicator can hold.

Quintero

Quintero discloses a microapplicator for dispensing and applying an adhesive or sealant material to a variety of surfaces, such as plastics, rubbers, wood, cement or even living tissue, to protect, seal or bond the surfaces together (*see* col. 12, lines 11-30 and col. 3, lines 35-40). The microapplicator is designed to deliver polymerizable materials that thicken and/or harden upon polymerization (col. 3, lines 41-42). As shown in Figure 1, the applicator contains a handle portion (112) and an applicator tip (120). The applicator tip (120) contains a microresevoir (122) that is designed to hold a very small amount of an adhesive or sealant material, in the order of 20 μL or less (col. 3, lines 25-31). Thus the applicator barrel (e.g. the handle portion) is not designed to contain a discrete chamber with a smaller diameter than the applicator barrel, as required by the claims.

Quintero's applicator is designed to be filled at its widest end. For example, when the handle potion contains or is in the form of a syringe, the barrel (112) is filled with the adhesive or sealant material and then the plunger is placed in the barrel (col. 10, lines 7-11). Further, Quintero explains that the adhesive or sealant material travels from the handle portion to the microreservoir by squeezing the handle portion (if it is formed of a flexible material) or gravitationally (col. 7, lines 12-17).

Quintero selects the geometry and materials for its applicator to stabilize the polymerizable material and to prevent it from polymerizing prematurely. For example, the tip may contain a polymerization initiator or accelerator, so that the polymerizable material contacts the initiator or accelerator immediately prior to application to the desired surface (see col. 4,

lines 1-7). Additionally, in some embodiments, the applicator contains a plug which contains a polymerization initiator or accelerator (see col. 4, lines 16-28). Thus, Quintero's applicator is designed to prevent breech filling of the applicator.

There is no disclosure or suggestion in the references to combine the references

There is no disclosure or suggestion in Fallon, Yeager or Quintero to combine these references. Fallon discloses a device for administering a hemostatic agent to tissue following surgery. Quintero discloses a device for administering a polymerizable material for use as a sealant or adhesive on a variety of surfaces. Yeager discloses an applicator for administering a medicament to a natural opening in the body. Different sized and shaped applicators are used for surgery, for applying a sealant to a surface and for administration of a medicament to natural openings in the body. Therefore one of ordinary skill in the art would not combine the teachings of Fallon with Yeager and/or Quintero.

Fallon in combination with Yeager and Quintero

Even if one of ordinary skill in the art combined Fallon with Yeager and Quintero, the applicator defined by claims 1-5 and the method of transvaginal or transrectal drug delivery defined by claims 6 and 8-10 would not be obvious.

Claims 1-5 are non-obvious

Fallon does not disclose or suggest an applicator that contains an applicator barrel which contains a discrete compartment, i.e. the medication chamber, within the applicator barrel, has a smaller diameter than the applicator barrel, and is designed to contain up to 1 mL of a pharmaceutical formulation. Contrary to the Examiner's assertion, the lumen (18) disclosed by

Fallon is not analogous to the medication chamber in the applicator defined by pending claims 1-5. As noted above, the lumen (18) forms one continuous space for containing a medicament. In contrast, the claim1 and its dependent claims specify that the applicator barrel contains a medication chamber with a smaller diameter than the applicator barrel. The medication chamber is a discrete section within the applicator barrel. Further, Fallon does not disclose or suggest an applicator that can be breech-filled, i.e. filled through the opening at the tip of the applicator.

Neither Yeager nor Quintero makes up for Fallon's deficiencies. Neither Yeager nor Quintero discloses an applicator containing an applicator barrel with a discrete medication chamber within the applicator barrel, where the medication chamber has a smaller diameter than the diameter of the applicator barrel and is designed to contain up to 1 mL of a pharmaceutical formulation. Yeager discloses an applicator with one continuous space that is filled to contain the medicament. While Quintero discloses a microreservoir for the storage and administration of a small volume of an adhesive or sealant material, the microreservoir is located in the applicator tip, which is *outside of the barrel* (112) in the handle portion.

Further, as noted above, both Yeager and Quintero teach away from devices that can be breech-filled. Yeager indicates that his design, which requires placing the medicament in through a large opening, is well-suited for automated filling. Similarly, Quintero's applicator is designed to be filled at its widest end (*see* col. 10, lines 7-11). Further, Quintero selects the geometry and materials for its applicator to stabilize the polymerizable material and to prevent it from polymerizing prematurely. For example, the applicator tip may contain a polymerization initiator or accelerator, which the polymerizable material contacts as it exits the applicator and is

applied to the desired surface. Thus, Quintero teaches away from modifying its applicator so that it is breech-filled with the adhesive or sealant material.

Therefore, claims 1-5 are non-obvious in view of Fallon in combination with Yeager and Quintero.

Claims 6 and 8-10 are non-obvious

With respect to the method claims, Fallon discloses a method for administering a hemostatic agent to tissue following surgery; Fallon does not disclose or suggest a method of transvaginal or transrectal drug delivery as defined by claims 6 and 8-10. Similarly Quintero does not disclose or suggest inserting the applicator into a patient's rectum or vagina, as required by the method claims. Further, as noted above, none of the references discloses or suggests breech-filling the applicator with 1 mL or less of a pharmaceutical formulation. In fact, each reference discloses filling the device or applicator at one end with the widest opening, and administering the formulation through a second, narrow opening at the opposite end of the device. There is no disclosure or suggestion in Fallon, Yeager and/or Quinetero to modify the devices to be breech-filled, as required by claims 6 and 8-10. Therefore, claims 6 and 8-10, as amended, are non-obvious in view of Fallon in combination with Yeager and Quinetero.

Allowance of claims 1-6 and 8-10, as amended, is respectfully solicited.

Respectfully submitted,

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